

Application No. 10/074,715 - - - - 4

REMARKS

Claims 12-18, 20-22, and 32 are pending in the present application.

Claims 1-11, 19, 23-31, 33, and 34 have been cancelled without prejudice.

Claims 12, 14, 20, and 22 have been amended.

Claim 12 has been amended to specify that the composition is suitable for preserving a blood sample for hormone analysis and that the composition is capable of preserving thyroid stimulating hormone in a blood sample for at least about 3 weeks at an ambient temperature of about 22 °C. The claim was also amended to include the limitation of cancelled claim 19 (i.e., an optional antifreeze agent). Support for this amendment can be found in the specification at page 7, lines 3-6 and 22-28, as well as in Example 3, page 11, line 13 through page 13, line 8, particularly in the data for stability at 22 °C in Tables 2, 3, and 4, and in Figures 1-3. No new matter is added by this amendment.

Claim 14 has been amended to specify that EDTA is ethylenediamine-tetraacetic acid and to include salts of EDTA. Support for this amendment can be found in the specification at page 5, lines 19-25. No new matter is added by this amendment.

Claims 20 and 22 have been amended to change the dependency from cancelled claim 19 to claim 12. Support for these amendments can be found in the original claims, since claim 19 depended from claim 12, and the limitations of claim 19 have been included in amended claim 12. No new matter is added by these amendments.

Rejections under the second paragraph of 35 U.S.C. §112.

Claim 14 stands rejected as being indefinite under the second paragraph of 35 U.S.C. §112 for reciting EDTA without defining the term. The claim has been amended to specify that EDTA is ethylenediaminetetraacetic acid. Accordingly, this rejection should be withdrawn. The other claims rejected for indefiniteness (i.e., 2, 6, 8, and 19) have been cancelled, rendering these rejections moot.

Rejections under 35 U.S.C. §102(e).

Claims 12-17 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,579,688 (Steaffens *et al.*). This rejection is unwarranted. Anticipation requires that a single prior art reference describe each and every limitation of a claim either explicitly or inherently. *Atlas Powder Co. v. IRECO Inc.*, 51 USPQ2d 1943, 1945-46 (Fed.

Application No. 10/074,715 - - - - - 5

Cir. 1999). Absence from the reference of any claimed element negates anticipation. *Rowe v. Dror*, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). Furthermore, the elements must be identically shown in the reference and must be arranged as in the claim, although this is not an *ipsissimis verbis* test. *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). When a claimed invention is not identically disclosed in a reference, and instead requires picking and choosing among a number of different options disclosed by the reference, then the reference does not anticipate. *Akzo N.V. v. International Trade Commission*, 1 USPQ2d 1241, 1245-46 (Fed. Cir. 1986). In addition, all words in a claim must be considered in judging the patentability of that claim against the prior art. *Application of Miller*, 169 USPQ 597, 600 (CCPA 1971). The foregoing conditions for anticipation are not satisfied in this instance.

Claim 12 is directed to a composition suitable for lysing and preserving a blood sample for hormone analysis. The composition consists essentially of *specified amounts* of a chelating agent, a cell lysing agent, a preservative, and an antifreeze agent, in water, the composition being capable of preserving thyroid stimulating hormone present in a blood sample for at least about 3 weeks at an ambient temperature of about 22 °C.

Steaffens *et al.* is directed to a reagent for stabilizing polypeptides and antigens used in analytical procedures. The Office Action cites scattered portions of the patent in support of the rejection. The cited portion at col. 3, lines 55-64 is merely a laundry list of possible components of the reagent, *one or more of which* could be present in the stabilizing composition:

"In certain preferred embodiments, the reagent comprises one or more of the following: buffer(s), blocking agent(s), solvent(s), salt(s), chelator(s), detergents(s), and preservative(s)."

The cited section at col. 4, line 33 to col. 5, line 6 merely defines each of the list components recited at col. 3, lines 55-64. The reference does not describe the claimed invention as arranged in the claim, and thus, does not anticipate claim 12. *In re Bond*, 910 F.2d at 832. In order to arrive at the invention embodied by claim 12, one must pick and choose from among the various options disclosed in the reference. This is not anticipation. *Akzo N.V. v. International Trade Commission*, 1 USPQ2d at 1245-46. Furthermore, the reference does not teach or even suggest a composition that is capable of preserving thyroid

Application No. 10/074,715 - - - - 6

stimulating hormone (TSH) in a blood sample for at least about 3 weeks at an ambient temperature of about 22 °C. The reference is silent with respect to TSH stability. All words in the claim must be considered in judging the patentability of that claim against the prior art. *Application of Miller*, 169 USPQ at 600. The same shortcomings apply equally to the rejections of dependent claims 13-17. The reference does not disclose a composition *consisting essentially of* the specific components set forth in the claims.

At best, the reference includes disjointed disclosures of individual options that could be combined. The actual examples provided by Steaffens *et al.* are directed to compositions quite different from those of the present claims (see Example 1, col. 11, line 45 through col. 12, line 39, as well as the compositions described at col. 6, lines 12-61). The composition of Example 1 includes a number of materials such as detergents, phosphate buffered saline (PBS), and bovine serum albumin (BSA), in addition to preservatives. The composition of Example 1 includes neither a cell lysing agent nor a chelating agent, both of which are required components of the compositions of the present claims. Similarly, the compositions in col. 6 include various buffers, fetal calf serum, glycerol, sodium chloride, various chelating agents, detergents, various preservatives, and sugars. There is no mention of a cell lysing amount of a cell lysing agent, nor any mention of preserving TSH for at least about 3 weeks in a blood sample.

Claim 12 is written in relatively closed "consisting essentially of" language. It is not nearly so broad as the cited sections of the Steaffens *et al.* patent. The broad, general disclosures of the reference fall far short of anticipation. The only specific teachings of the reference are directed toward compositions that are significantly different from the presently claimed inventions. The reference does not disclose all limitations of the claims and does not disclose the claimed invention in the manner set forth in the claims. Accordingly, claims 12-17 are not anticipated by Steaffens *et al.*

Rejections under 35 U.S.C. §103(a).

Claims 20-22 and 32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,579,688 (Steaffens *et al.*) in view of U.S. Patent No. 5,616,460 (Figard). This rejection is also unwarranted. A *prima facie* case for obviousness requires that the references themselves must contain some teaching, suggestion, or

Application No. 10/074,715 - - - - 7

motivation to combine their teachings. *In re Bell*, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993); *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Moreover, an obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). Neither prong of this analysis has been satisfied in this instance. Furthermore, a *prima facie* case for obviousness requires that all claim limitations be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). As noted above, all words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 165 USPQ at 496. The instant rejection falls short of these requirements.

Each of claims 20-22 and 32 includes all of the limitations of claim 12. As noted above, Steaffens *et al.* do not teach or suggest a composition as set forth in the present claims that is capable of preserving TSH within a blood sample for at least about 3 weeks at 22 °C. The same is true for Figard. Furthermore, while the references disclose the various classes of compounds specified by the claims, in isolation, there would have been no motivation in the references themselves for one of ordinary skill in the art to combine the isolated teachings of the references to obtain the *specific compositions* of the present claims. The fact that the Examiner has done so is evidence of impermissible hindsight reconstruction of the claimed invention using Applicants' own specification as a guide.

There certainly would have been no reasonable expectation of success in preserving TSH in a blood sample for at least about 3 weeks in such a combination, since the references are silent with regard to preservation of TSH. In addition, the compositions of Figard require the presence of dithioerythritol for protecting sulfhydryl groups in a protein from oxidation (see col. 4, lines 33-52). The relatively closed language of the present claims excludes this material, unless it was shown to be a chelating agent, cell lysing agent, a preservative, or an antifreeze agent, or was present in a non-functional amount. The references do not provide guidance as to whether dithioerythritol falls within the listed components in the present claims.

In view of the foregoing, it is clear that claims 20-22 and 32 would not have been obvious in view of the applied combination of references.

Application No. 10/074,715 - - - - 8

Conclusions.

Applicants note that claim 18 was not included in either ground for rejection. Since claim 18 includes all of the limitations of claims 12 and 17, it is neither anticipated by Steaffens *et al.*, nor rendered obvious by Steaffens *et al.* in view of Figard; neither of these references, either alone or in combination, disclose all of the elements of the claim.

None of the present claims are anticipated nor would would any of the claims have been obvious over the applied references. Accordingly, Applicants request that all rejections be withdrawn and the application be passed to issuance.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this AMENDMENT AND RESPONSE UNDER RULE 111 is being transmitted by facsimile transmission to Fax No. 703-872-9306 on March 3, 2005.

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